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VB

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/327,230	06/07/99	GRAY	J EXAMINER 8-4A

000826
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HM22/0226

ART UNIT	PAPER NUMBER
NELSON, A	11

DATE MAILED:
1638

02/26/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/327,230	Gray et al.
Examiner	**Group Art Unit**
Amy Nelson	1638

☒ Responsive to communication(s) filed on *Jan 16, 2001*.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-24* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-24* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *7*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Information Disclosure Statement filed 1/16/01 has not been considered because copies of the references were not provided. Applicant is kindly requested to provide copies of the cited references. Although Applicant indicates that the Information Disclosure Statement and copies of the references were originally filed on 10/4/99, they have not been received into the application. Applicant is asked to provide copies of the references, along with the postcard receipt and original Information Disclosure Statement filed 10/4/99.

Claim Rejections - 35 USC § 112

2. Claims 1, and 9-23 remain rejected and new Claim 24 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth in the last Official action mailed 8/11/00. Applicant's arguments filed 1/16/01 have been fully considered but they are not persuasive.

Applicant asserts that the claims have been amended to limit to SEQ ID NO:1, and therefore the rejection is no longer applicable (response, p. 4). Examiner responds that new Claim 24 encompasses other sequences than SEQ ID NO:1, and therefore the rejection is still appropriate.

Applicant argues that a written description rejection should not be based on the presence or absence of a working example, and hence the instant rejection is misplaced (response, p. 4). Examiner responds that a written description rejection is based on whether or not Applicant has adequately described the invention. As Applicant has not described a promoter sequence, the invention is not adequately described.

Applicant also argues that Applicant has described the 5' upstream region of the *ils1* gene, and indicated that a transription start site occurs at nucleotide 3115, and hence Applicant describes a promoter region that extends upstream of nucleotide 3114. Further, Applicant describes driving gene expression in a plant cell with the sequence of SEQ ID NO:1 (response, p. 5). Examiner reiterates that Applicant has not provided definitive evidence of promoter activity for SEQ ID NO:1, and hence Applicant has not described a promoter. It is noted that Claims 2-8, as they recited "nucleotide sequence," are adequately described.

Applicant asserts that the described 2822 bp of SEQ ID NO:1 corresponds to the upstream region of the *ils1* gene. It would be expected that the region responsible for activating and driving expression would be within this region (response, p. 5). Examiner responds that enhancer and inhibitor elements can occur at great distances from the transcription start site. Further, elements responsible for spatial, temporal or developmental regulation can occur in an upstream region which can eliminate promoter activity. Finally, extremely weak promoters would not be effective for expression of a heterologous gene. Therefore, it is maintained that Applicant has not described a promoter.

3. Claims 1-23 remain rejected and new Claim 24 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reasons of record as set forth in the last Official action mailed 8/11/00. Applicant's arguments filed 1/16/01 have been fully considered but they are not persuasive.

Applicant asserts that Applicant need not describe how the invention works, and Applicant need not provide a working example of every permutation of the invention (response, p. 6). Examiner responds that the question is not how the invention works, but rather that the invention works. While Applicant need not provide a working example for every permutation of the claimed invention, Applicant need provided a working example of at least one permutation of the claimed invention, or enough guidance to practice the claimed invention in the absence of a working example. Applicant has provided neither.

Applicant asserts that the amended claims are limited to SEQ ID NO:1, and the specification fully enables one of skill in the art to make this composition (response, p. 6-7). Examiner responds that although Applicant has taught how to make a nucleotide sequence comprising SEQ ID NO:1, Applicant has not taught how to use the nucleotide sequence. Further, new Claim 24 is directed to nucleotide sequences which hybridize to SEQ ID NO:1 under stringent conditions, and Applicant has not taught other nucleotide sequences with promoter activity.

Applicant argues that the specification teaches that SEQ ID NO:1 is a promoter and can be used to drive expression of operably linked coding sequences. SEQ ID NO:1 is 2822 bp and is located upstream of a gene which is expressed in plants. Also, there are many examples in the art of active promoters of less than 1.2 kb (response, p. 7). Examiner responds that the teaching in the specification of SEQ ID NO:1 being a promoter is prophetic. The specification has provided no evidence of promoter activity for the disclosed nucleotide sequence. The existence of promoter activity in small upstream regions of other genes does not speak to the instant invention. Regulation of gene expression is complex and often involves multiple enhancer and/or inhibitor elements. Hence, it is imperative that Applicant provide guidance for the precise region capable of inducing expression of an operably linked coding region.

Applicant further asserts that both the cited Benfey reference and the cited Kim reference teach promoters of several hundred bases, and hence do not provide evidence of plant regulatory sequences located several thousand bases from the transcription start site (response, p. 7). Examiner responds that the purpose of the Benfey and the Kim references is to exemplify the fine structural and functional regulation of promoter sequences, wherein even a single nucleotide change can completely abolish promoter activity. Hence, it is critical that empirical evidence be provided by Applicant of promoter activity by the disclosed upstream region.

Lastly, Applicant argues that promoter activity can be determined by assaying for expression of an operably linked reporter gene (response, p. 7-8). Clearly, the most effective way of assessing promoter activity is by operable linkage to a reporter gene, and measurement of

reporter gene expression in transgenic cells or plants. However, such assessment is far from routine experimentation, but would require undue trial and error experimentation to test the myriad of different sized fragments from different regions of the upstream region, and to screen through the vast number of transformed cells, tissues, or plants, to identify those upstream regions which possess promoter activity. Therefore, the invention is not enabled.

4. Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At Claim 24, lines 2-3, the phrase "stringent conditions" is indefinite because "stringent" is a relative term, and hence it is not known what is encompassed by the phrase. Appropriate correction is required to clarify the metes and bounds of the claimed invention.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy J. Nelson whose telephone number is (703) 306-3218. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310. The fax phone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application, or if the examiner cannot be reached as indicated above, should be directed to the legal analyst, Yolanda Vines, whose telephone number is (703) 305-2365.

Amy Nelson

AMY J. NELSON, PH.D
PRIMARY EXAMINER

Amy J. Nelson, Ph.D.
February 20, 2001